REMARKS

Claims 48, 49, 51, 52, 54, 55, and 57-60 are pending in the application and under active consideration. Claims 47, 50, 53, and 56 have been canceled without prejudice or disclaimer. New claims 59 and 60 have been added.

Claim 48 has been amended to make explicit that the polynucleotide comprises a coding sequence for a multiple epitope fusion antigen comprising the amino acid sequence of SEQ ID NO:5, or an amino acid sequence with at least 90% sequence identity thereto, wherein the multiple epitope fusion antigen reacts specifically with anti-HCV antibodies present in a biological sample from an HCV-infected individual, wherein the antibodies bind to an epitope of SEQ ID NO:5. Support for the amendment can be found in the specification, for example, at page 8, lines 28-30; page 9, lines 4-5; page 10, lines 1-2; page 13, lines 20-30; page 21, lines 8-12; Figures 7A-7F, and the Sequence Listing at pages 14-17. Accordingly, the specification provides adequate support for this amendment. Entry of the amendment is respectfully requested.

Claim 49 has been amended to make explicit that the polynucleotide comprises a coding sequence for a multiple epitope fusion antigen consisting of the amino acid sequence of SEQ ID NO:5. Support for the amendment can be found in the specification, for example, at page 8, lines 28-30; page 9, lines 4-5; page 10, lines 1-2; Figures 7A-7F, and the Sequence Listing at pages 14-17. Accordingly, the specification provides adequate support for this amendment. Entry of the amendment is respectfully requested.

Support for new claims 59 and 60 can be found in the specification, for example, at page 28, lines 9-10, Figures 7A-7F, and the Sequence Listing at pages 10-14. Accordingly, the specification provides adequate support for new claims 59 and 60. Entry of the new claims is respectfully requested.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Objections to the Specification

Abstract

The abstract of the disclosure has been amended to include the subject matter of the claims, which are drawn to polynucleotides encoding a multiple epitope fusion antigen for use in an assay for the simultaneous detection of HCV antigens and antibodies present in a sample. Support for the amendment to the Abstract can be found in the specification, for example, at page 7, lines 22-30; page 34, lines 12-26; and pages 38-42. Entry of the amendment and withdrawal of the objection to the abstract is therefore respectfully requested.

Title

The title has been revised as suggested by the Examiner to reflect the election of claims directed to polynucleotides encoding a multiple epitope fusion antigen for use in an HCV antigen/antibody combination assay. Withdrawal of the objection to the title is therefore respectfully requested.

Objections to the Claims

Claims 47-49 have been objected to for referring to figures in the application. Claim 47 has been canceled; therefore, the objection to this claim is moot. Claims 48 and 49 have been amended to remove references to figures and to instead recite the sequence of SEQ ID NO:5

35 U.S.C. § 101

Claims 53-58 have been rejected under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter. In particular, the Office Action alleges:

> While it is recognized that the claimed polynucleotide is not a product of nature, the claims do read on human beings, whose cells have been transformed with the vector. (Office Action, page 4.)

Claims 53-55 have been amended to make explicit that the host cell is an isolated host cell. Therefore, claims 53-55 and all claims dependent therefrom are directed to statutory subject matter, and withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.

35 U.S.C. § 112, second paragraph

Claims 47-58 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Office Action, pages 4-5).

(a) The Office Action alleges that claims 49, 52, 55, and 58 are indefinite because the claims relate to polynucleotides comprising a sequence coding for the amino acid sequence of Figures 5A-5F of the application; however, Figure 5 does not describe an amino acid sequence. To expedite prosecution, claim 49 has been amended to make explicit that the polynucleotide comprises a coding sequence for a multiple epitope fusion antigen consisting of the amino acid sequence of SEQ ID NO:5.

(b) The Office Action alleges that claims 47, 48, 50, 51, 53, 54, 56, and 57 are indefinite because the claims relate to polynucleotides encoding polypeptides comprising amino acid sequences of at least 80% identity to SEQ ID NO:4 which react specifically with anti-HCV antibodies, and it is unclear if the claims are requiring that the antibodies react with any portion of the multiple epitope fusion antigen or if the claims are requiring that the antibodies react specifically with a portion of the multiple epitope fusion antigen sequence having the sequence of SEQ ID NO:4. Claim 47 has been canceled; therefore, the rejection with respect to this claim is moot. To expedite prosecution, claim 48 has been amended to make explicit that the anti-HCV antibodies present in the biological sample from an HCV-infected individual bind to an epitope of SEQ ID NO:5.

For at least these reasons, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

35 U.S.C. § 112, first paragraph, Written Description

Claims 47, 48, 50, 51, 53, 54, 56, and 57 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of an adequate written description. In particular, the Office Action alleges that specification does not provide support for the large genus of multiple epitope fusion proteins recited in the claims (Office Action, pages 7-8). The Office Action further alleges that "while the claims require that the proteins are able to react with anti-HCV antibodies, there is no

indication that any protein within the structural limitations of the claims would be capable of performing this function" (Office Action, page 7). The Office Action further cites Riffkin et al. (Gene (1995) 167:279-283) and Bowie et al. (Science (1990) 247:1306-1310) in support of the position that protein chemistry is unpredictable and "modification of a single residue in a protein sequence can change the immunogenic properties of a protein" (Office Action, page 7). The Office Action also alleges that "[i]t is not clear from the application what structures, residues, or regions in the claimed sequences must be maintained for the compositions to induce an anti-HCV response (Office Action, page 8). Applicants respectfully traverse the rejection on the following grounds.

The fundamental factual inquiry in written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Determining whether the written description requirement is satisfied is a question of fact and the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim,* 191 USPQ 90 (CCPA 1976). It is not necessary that the application describe the claimed invention *in ipsis verba.* Rather, all that is required is that the specification reasonably convey possession of the invention. *See, e.g., In re Lukach,* 169 USPQ 795, 796 (CCPA 1971). Finally, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange,* 209 USPQ 288 (CCPA 1981).

Furthermore, the Patent Office's own guidelines on written description are clear -- the written description requirement is highly fact-dependent and there is a strong presumption that an adequate written description of the claimed invention is present at the time of filing:

> [t]he description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical

> properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. ... A "representative number of species" means that the species that are adequately described are representative of the entire genus. ... What constitutes a "representative number" is an inverse function of the skill and knowledge of the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. ... Description of a representative number of species does not require the description be of such specificity that it would provide individual support for each species that the genus embraces. (Final Examiner Guidelines on Written Description, 66 Fed. Reg. 1099, emphasis added).

Simply put, there is absolutely **no** requirement that Applicants exemplify (or reduce to practice) every sequence falling within the scope of the claims in order to adequately describe the polynucleotides encoding multiple epitope fusion antigens comprising the amino acid sequence of SEQ ID NO:5 or variants thereof, as claimed. Rather, the test is whether the specification contains sufficient disclosure regarding structural and functional characteristics of the claimed sequences to satisfy the written description requirement. In the pending case, the specification as filed more than adequately describes the structure and function of the claimed polynucleotides.

The specification as filed fully describes the claimed subject matter. The claims, as currently amended, clearly recite both the structure (*e.g.*, a polynucleotide comprising a coding sequence for a multiple epitope fusion antigen comprising the amino acid sequence of SEQ ID NO:5, or an amino acid sequence with at least 90% sequence identity thereto) and function (the encoded multiple epitope fusion antigen reacts specifically with anti-HCV antibodies present in a biological sample from an HCV-infected individual) of the recited polynucleotides. In addition, claim 48 has been further amended to make explicit that the anti-HCV antibodies present in the biological sample bind to an epitope of SEQ ID NO:5. Therefore, when properly construed, it is plain that only polynucleotide sequences having the recited structure and function are encompassed by the pending claims. The written description requirement is satisfied because the specification describes sufficient structural and functional characteristics of the claimed molecules.

Given the information provided by the sequence of SEQ ID NO:5, one of skill in the art would be able to routinely identify a polynucleotide encoding the amino acid sequence of SEQ ID NO:5 or an amino acid sequence with at least 90% sequence identity thereto. See the specification, for example, on page 17, line 28 through page 19, line 2, where it is noted how to determine sequences falling within the requisite percent identity. At the time of filing of the instant application, determining sequence identity was routine. Furthermore, numerous sequences from different HCV strains that can be used in the practice of the invention are described in the specification, for example, at page 11, line 21 through page 12, line 2; page 16, lines 5-7; and page 28, lines 3-8. The specification also provides guidance on methods of identifying polynucleotides that encode multiple epitope fusion antigens that react specifically with anti-HCV antibodies present in a biological sample from an HCV-infected individual. See the specification, for example, at page 34, lines 12-26, which describes detection of antibodies from a biological sample that bind the multiple epitope fusion antigen; and Example 1, which describes antigen-based assays for detection of antibodies.

Applicants further note that the limitations of the claims do not require that the multiple epitope fusion antigens encoded by the recited polynucleotides have all the biological activities of the individual HCV polypeptides included in the fusion. The claims recite polynucleotides encoding multiple epitope fusion antigens comprising a polypeptide that "reacts specifically with anti-HCV antibodies present in a biological sample from an HCV-infected individual." Sequences that do not encode a polypeptide that "reacts specifically with anti-HCV antibodies" are not encompassed by the claims.

It is axiomatic that the specification need only describe in detail that which is new or not conventional. (See, Guidelines on Written Description, page 275). In the case at hand, a skilled artisan reading the specification would have known that Applicants were in possession of claimed polynucleotides as recited in the claims in view of the specification's extensive disclosure of (1) precise sequences falling in the scope of the claims; (2) conventional, known methods of aligning polynucleotides or polypeptides; and (3) conventional, known methods of testing polypeptides for antibody binding. In view of the disclosure of the specification and state of the art, it would have been plain to the skilled artisan that Applicants were in possession of the claimed invention at the time the specification was filed.

Applicants further direct the Examiner's attention to the Patent Office's own guidelines regarding the written description requirement. Example 14 of the Patent Office's "Synopsis of Application of Written Description Guidelines" is clear that a **single** disclosed species may be representative of a "product-by-function" genus when all members exhibit structural identity to a reference compound (here, SEQ ID NO:5) and when an assay is provided for identifying all variants having the claimed activity (such as detailed in the specification, for example, at page 34, lines 12-26, and Example 1). Example 14 is reproduced below:

> **Claim**:
> A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→ B.
>
> **Analysis:**
> ... The procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art. ....
>
> There is actual reduction to practice of a single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO:3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO:3. The **single species disclosed** is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.
>
> **Conclusion:** The disclosure meets the requirements of 35 U.S.C. § 112, first paragraph as providing adequate written description for the claimed invention. (Example 14, emphasis added.)

Like Example 14, applicants in the pending case have provided a limit to the structural identity (90% identity), a specified activity of the variants (encode polypeptide that reacts specifically with anti-HCV antibodies present in a biological sample from an HCV-infected

individual) and methods for identifying constructs exhibiting the specified activity (See, *e.g.*, assay described at page 34, lines 12-26 and Example 1 of the application). Therefore, as in PTO Example 14, the multiple species disclosed in the application are representative of the genus as a whole.

Moreover, Examiner Christopher Low, in a presentation at the BioScience Forum on Thursday, September 9, 2004, indicated that similar claims to nucleic acid variants also satisfy the written description requirement. *See, e.g.,* slide #17 of Examiner's Low presentation, where the exemplary claim reads:

> An isolated and purified nucleic acid comprising a nucleotide sequence that is 90% identical to SEQ ID NO:1, wherein said nucleic acid encodes a protein having activity X.

Indeed, the exemplary claim presented in Examiner Low's presentation is the polynucleotide equivalent of the claim presented in Example 14 of the PTO's "Synopsis of Application of Written Description Guidelines." Both of these exemplary claims are considered adequately described in view of a specification that discloses examples of sequences having the claimed activity and methods of determining the presence or absence of such activity.[1]

Accordingly, one of skill in the art would conclude applicant was in possession of the necessary common attributes possessed by the members of the genus, and it is clear that, as concluded in PTO Example 14 and the Example presented by Examiner Low, the present application provides adequate written description for the substance of claims 47, 48, 50, 51, 53, 54, 56, and 57.

For at least the above reasons, withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

35 U.S.C. § 103

Claims 47, 48, 50, 51, 53, 54, 56, and 57 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the reference of Valenzuela et al. (WO 97/44469; hereinafter

[1] In addition, Applicants note how their description of particular sequences and recitation of these sequences in the claims distinguishes the pending case from *University of California v. Eli Lilly*. In *Eli Lilly*, the claims failed to recite any reference sequence whatsoever and, therefore, the genus encompassed by the claims included any

"Valenzuela") in view of Chien et al. (Vir. Hepat. Liver Dis. (1994) 320-324; hereinafter "Chien"), Puntoriero et al. (EMBO J. (1998) 17:3521-3533; hereinafter "Puntoriero"), and Hartman et al. (U.S. Patent No. 6,001,604; hereinafter "Hartman"). Valenzuela is cited for teaching a multiple epitope fusion antigen comprising various epitopes from the HCV polyprotein, including antigenic regions 72-89, 395-441, 444-490, 493-539, 580-615, and 618-653. Puntoriero is cited for teaching a generic HVR consensus sequence varying from that of MEFA 12 residues 113-143 by one residue (position 120). Chien is cited for teaching an HCV core protein epitope sequence and subtype variations of the core region. The Office Action alleges that it would have been obvious to combine the references of Valenzuela and Puntoriero because "Valenzuela teaches that any E2 HVR consensus sequence may be used in the MEFAs described therein, and Puntoriero discloses such a sequence" (Office Action, page 12). The Office Action also alleges that that it would have been obvious to combine the references of Valenzuela and Chien because "the art discloses the sequences comprising residues 67-84 as comprising sequences recognized by anti-HCV antibodies" (Office Action, page 12). The Office Action further alleges that the combined teachings of the references suggests a multiple epitope fusion antigen that would have 80-90% identity to the sequence in Figure 7:

> The combined teachings of these references would result in peptides varying from the peptide of MEFA12 in: 18 spacer residues, 6 residues of the hSOD leader (69-63), one residue in the E2 HVR1+2 sequence, 19 residues in the c33c sequence, 4 residues in the C100 sequence, 4 residues in the two sequences 9-53 (representing the addition of residue 9 in MEFA 12, and the substitution of residue 47) and 14 residues (combined) in the other core epitopes (representing the addition of residues 64-66, and 85-88 two times). Thus, the MEFA suggested by the art and MEFA 12 vary by about 66 residues, assuming that it is not obvious to include the spacers residues or the additional residues in the regions 9-53 and 64-88. Because this results in a MEFA varying from the sequence of Figure 7 (MEFA 12) by less than 82 residues, it indicates that the combined teachings of these references render obvious MEFA proteins of 90% or 80% identity to MEFA 12 (Office Action, pages 12-13.)

Applicants respectfully traverse the rejections under 35 U.S.C. § 103 and the Office's purported facts underlying the rejections on the following grounds.

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polynucleotide encoding insulin. In contrast, the genus encompassed by the pending claims is fully described because every sequence exhibiting 90% identity can be envisioned from the reference sequences.

Valenzuela fails to teach or suggest a polynucleotide comprising a coding sequence for a multiple epitope fusion antigen comprising the amino acid sequence of SEQ ID NO:5 or an amino acid sequence with at least 90% sequence identity thereto. The sequence of SEQ ID NO:5 consists of 829 amino acids that differ from the sequence of MEFA 6, disclosed by Valenzuela, in multiple places. In particular, SEQ ID NO:5 includes 15 residues from an E2 HVR type 1a consensus region (residues 390-404) and 31 residues from E2 HVR types 1 and 2 (residues 384-414) consensus regions, which are not present in MEFA 6. In contrast, MEFA 6 contains a single E2 region (residues 405-444) that encompasses different residues than the E2 regions of MEFA12. Furthermore, Valenzuela does not teach or suggest coupling E2 HVR consensus sequences for type 1a, type 1, and type 2 strains as in the instant invention. In addition, SEQ ID NO:5 contains 42 residues from core epitopes that are also not included in MEFA 6. As acknowledged by the Examiner, the choice of linkers, SOD truncation, and precise regions of other HCV polypeptides included in the MEFAs also differ (Office Action, page 12). Thus, the MEFA 6 taught by Valenzuela clearly has less than 90% sequence identity to the MEFA 12 of the instant application.

Contrary to the Examiner's assertions (Office Action, page 12), Puntoriero does not teach or suggest the sequence from residues 92-143 of SEQ ID NO:5 that contains the E2 HVR regions. SEQ ID NO:5 differs from the consensus sequence presented at page 3522 of Puntoriero at multiple positions: Phe 101 is a Leu, Val 102 is a Thr, Ala 106 is a Ser, Lys 110 is a Ser, and Ala 120 is a Ser in the consensus sequence of Puntoriero. Furthermore, none of the other sequences shown in the alignment at page 3522 of Puntoriero are identical to the HVR sequences of MEFA 12. Nor does Puntoriero teach or suggest the same boundaries for the HVR region as contained in MEFA12. The E2 HVR region in MEFA 12 begins at position 7 of the Puntoriero consensus sequence, and the Puntoriero consensus sequence does not include residues 140-143 of SEQ ID NO:5. Nor does Puntoriero teach or suggest linking HVR regions from more than one strain, nor the particular residue ranges that are coupled in MEFA 12. The focus of Puntoriero, on the contrary, is on identifying HVR mimotopes that react with sera of patients infected with HCV; therefore, Puntoriero fails to provide any motivation for combining HVR sequences in the manner of the instant invention.

Contrary to the Examiner's assertions (Office Action, page 12), Chien fails to describe or suggest the sequences consisting of residues 64-88 or 9-53 of the core region, which are present in MEFA 12. Nor does Chien suggest linking core epitopes consisting of residues 9-53, 64-88, and 67-84 from HCV strains 1 and 2 in a multieptiope fusion antigen as in the instant invention. Since the focus of Chien is on the identification of serologically distinct subtypes of HCV, not on the construction of multieptiope fusion antigens, Chien fails to provide any motivation for combining sequences in the manner of the instant invention.

Hartman pertains to production of recombinant insulin. Although Hartman describes the use of a truncated SOD leader sequence to improve expression of insulin, Hartman fails to teach or suggest the particular truncated SOD sequence consisting of residues 1-69 of the instant invention (Hartman describes using a 62 residue SOD leader). Moreover, Hartman fails to describe or suggest any method for expression of any gene other than insulin. Nowhere does Hartman even mention HCV or production of multiple epitope fusion antigens. The presumption that methods of expressing insulin are necessarily applicable to other genes is unsupported. It is well known in the art that methods that result in efficient expression of one gene do not necessarily work well for expression of another gene; hence, the wide array of expression vectors that are commercially available. Hartman fails to demonstrate that expression of HCV multiple epitope fusion antigens can be improved by a truncated SOD leader sequence. Therefore, any suggestion that genes other than insulin would be successfully expressed by the methods described by Hartman is unsupported by any experimental evidence.

It is axiomatic that statements in the prior art must be considered in the context of the teaching of the entire reference, and that rejection of claims **cannot** be predicated on mere identification in a reference of individual components of claimed limitations. In this regard, the Federal Circuit has consistently reversed a finding of obviousness, even when all claimed elements are individually present in the references. *See, e.g., In re Kotzab* 217 F.3d 1365, 55 USPQ2d 1313, 1317 (CAFC 2000, emphasis added):

> While the test for establishing an implicit teaching, motivation or suggestion is what the combination of these two statements [in the reference] would have suggested to those of ordinary skill in the art, the two statements cannot be viewed in the abstract. Rather, they must be considered in the context of the teaching of the entire reference. Further, a rejection **cannot** be predicated on the mere identification [in the reference] of individual

components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

Virtually all inventions are combinations of elements that can be individually identified in multiple references. See, e.g., *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) noting that the Office cannot rely on a high level of skill in the art to overcome the differences between the selected elements in the references, it cannot rely on a high level of skill in the art to provide the necessary motivation; *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), affirming that common knowledge and common sense are not the specialized knowledge and expertise necessary to establish a motivation to arrive at the claimed invention.

Thus, the requirement is not whether each claimed element can be identified individually in a reference but, rather, whether the Examiner can show "reasons that the skilled artisan, confronted with the same problem as the inventor, and with no knowledge of the claimed invention, would select the elements from the cited prior art reference for combination in the manner claimed." *In re Rouffet*, 47 USPQ2d at 1458. In the pending case, the Office has not met this burden.

As explained in Section 2143.01 of the MPEP, the mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Since the suggestion or motivation to combine the references to arrive at the claimed invention is not in the references, the Examiner is required to cite to some knowledge generally available to one of ordinary skill in the art for the motivation to combine the references. (MPEP2143). It is respectfully submitted that the Examiner has not provided such knowledge. Instead, the Examiner has asserted that because (1) Valenzuela teaches an HCV multiple epitope fusion antigen (having less than 90% identity to SEQ ID NO:5), (2) Puntoriero teaches E2 HVR consensus sequences (but not the sequence contained within SEQ ID NO:5), (3) Chien teaches core epitope sequences (which are not included in the MEFAs taught by Valenzuela), and (4) Hartman teaches truncated hSOD leader sequences (but not the 69 truncated SOD leader used in the instant invention), it would have been obvious to combine the references to produce polynucleotides encoding the multiple epitope fusion antigens of the invention.

Without a suggestion to modify the references evident in the prior art, as well as a lack of a reasonable expectation of success, the only conclusion supported by the record is that the rejection was made impermissibly using hindsight reconstruction of the invention. As stated by the Court of Appeals for the Federal Circuit, "[i]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). As also stated by the Court of Appeals for the Federal Circuit "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). Therefore, the Office has not met the requirements for a *prima facie* showing of obviousness under 35 U.S.C. § 103.

For at least the above reasons, withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In light of the above remarks, Applicant submits that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicant invites the Examiner to contact the undersigned.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

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